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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,506	11/22/2000	Thomas R. Cech	015389-002616US	5211
34151	7590	06/16/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW LLP			SISSON, BRADLEY L	
8TH FLOOR			ART UNIT	
TWO EMBARCADERO CENTER			PAPER NUMBER	
SAN FRANCISCO, CA 94111			1634	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/721,506

Applicant(s)

CECH ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 73,75-78,80,81,83-86,88,91-94,96 and 101-104 is/are pending in the application.
- 4a) Of the above claim(s) 73,80,81,88,89 and 96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75-78,83-86,91-94 and 101-104 is/are rejected.
- 7) ☒ Claim(s) 101-104 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                     | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2005 has been entered.

### ***Election/Restrictions***

2. Claims 73, 80, 81, 88, 89, and 96 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06 November 2003.

### ***Claim Objections***

3. Claims 101-104 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As presently worded claim 75, the independent claim from which claims 101-104 depend, stipulates that the encoded protein is to have " sequence that

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is at least 80% identical to the full length of SEQ ID NO: 2.” Claims 101-104 effectively broaden the scope of claim 75 in that the amino acid sequence is to be 95% or 98% identical to an area of but 100 or 500 contiguous amino acids of SEQ ID NO: 2. With SEQ ID NO: 2 comprising 1132 amino acids, claims 101 through 104 seemingly allow for the presence of fragments of peptide set forth in Claim 75, proteins of 100 to 500 residues in length. Also, claims 101-104 seemingly broaden the scope over which the area of identity is based from one where it requires the full length, to one where but 100 to 500 residues are considered.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 75-78, 83-86, 91-94, and 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) (“the description must clearly allow persons of

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ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

6. Claims 75, 83, and 91, the three independent claims under consideration, have been amended so to recite added limitations as to the percent identity and the length over which it is to be determined. A review of the specification fails to find support for this limitation and a review of the disclosure also fails to identify where attention has been directed to any supporting passage. Accordingly, the limitations added to claims 75, 83, and 91 constitute new mater.

7. For the above reasons and in the absence of convincing evidence to the contrary, claims 83-86, 91-94, and 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 101-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 101-104 all depend from claim 75, which stipulates that the percent identity is be based upon the full length of the protein, however, claims 101-104 stipulate that the area of identity is to be based upon 100 to 500 contiguous amino acids. When the protein in question is over 1100 amino acid residues in length, the comparison of but 100 to 500 contiguous residues seemingly is in conflict with re requirement of claim 75.

***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 75-78, 83-86, 91-94, and 101-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,337,200. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 75, 83 and 91 of the instant application fairly encompass the nucleic acid of claims 1-6 of the '200 patent.

13. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 24-28, 30, 34, and 35 of copending Application No. 09/438,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to isolated nucleic acid that encodes hTERT.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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14. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/054,295. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims fairly encompass nucleic acid that encodes hTERT.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-26, 69, 70, 81, and 82 of copending Application No. 09/721,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to polynucleotide/nucleic acid that encodes hTERT.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 19, and 21-23 of copending Application No. 10/044,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an isolated nucleic acid. While the claimed composition of claim 1 in the '692 application is defined as being "an immunogenic composition," it need only comprise the nucleic acid.

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Accordingly, claims drawn to a nucleic acid or to a composition that comprises same, when only are obvious one over the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-14, and 23-25 of copending Application No. 10/877,124. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims fairly encompass isolated nucleic acid that encodes hTERT.

18. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

19. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
13 June 2005